

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA

v.

MARK RAINERI

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§
§
§
§

Criminal No.

16CR0456

United States District Court
Southern District of Texas
FILED

OCT 07 2016

David J. Bradley, Clerk of Court

INFORMATION

The United States charges:

INTRODUCTION

At all times material to this Indictment:

1. The United States Food and Drug Administration (FDA) is the federal agency charged with protecting the health and safety of the American public by ensuring that drugs sold to the public are safe and effective for their intended uses and that they bear labeling that enables consumers to use them in a safe manner. The FDA's responsibilities include regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce. To meet those responsibilities the FDA enforces statutes which require that drugs bear labels and labeling that enable customers to use them in a safe manner and that drugs are manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 §§ 352(f), 352(o) and 360 (c).

2. To legally introduce, deliver for introduction, or cause the delivery or introduction for delivery of a drug into interstate commerce, a person is required to comply with all applicable provisions of the Federal Food, Drug and Cosmetic Act (FDCA) and its implementing regulations found in Title 21 of the Code of Federal Regulations.

3. The FDCA's definition of "drugs" includes articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or an article (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of such articles. 21 U.S.C. § 321(g)(i).

4. The FDCA prohibits the introduction of "misbranded" drugs into interstate commerce. 21 U.S.C. § 331.

5. "Misbranding" includes any of the following conduct:

(a) dispensing, without a prescription, a drug intended for use by man which, because of its toxicity or potential for harmful effect, was not safe for use except under supervision of a licensed practitioner. 21 U.S.C. § 353(b)(1).

(b) where a drug's labeling does not bear adequate directions for use, 21 U.S.C. § 352(f)(1);

(c) where the drug was manufactured, prepared, propagated, compounded or processed in an establishment not registered with the Secretary of Health and Human Services, 21 U.S.C. § 352(o); or

(d) false or misleading labeling of a drug in any particular, 21 U.S.C. § 352(a).

6. The introduction or delivery for introduction into interstate commerce of a "misbranded" drug with intent to defraud or mislead the consumer or a federal regulatory agency is a felony. 21 U.S.C. § 333(a)(2).

7. "Etizolam" is a non-FDA approved pharmaceutical, and the office of Diversion Control states that Etizolam does not currently have an accepted medical use in the United States. Etizolam is a chemical analogue of Benzodiazepine.

8. There was an illegitimate market for Etizolam in the United States and illegal distribution was facilitated by delivery of the drug from India through interstate commerce.

INTENT TO DEFRAUD OR MISLEAD

9. It was a part of the intent to defraud or mislead the U.S. Postal Inspectors that Mark Raineri obtained packages of Etizolam which contained false customs declarations that were mislabeled to pass through United States customs inspection.

COUNT ONE


17. Paragraphs 1 through 9 are incorporated herein as if fully set forth.

18. On or about May 26, 2016, in the Southern District of Texas and elsewhere, the defendant, MARK RAINERI, with the intent to defraud and mislead, did cause the delivery for introduction into interstate commerce of a drug, Etizolam, that is adulterated or misbranded, by preparing, propagating a drug and processing a drug in an establishment not registered with the Secretary of Health and Human Services, 21 U.S.C. § 352(o).

In violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

KENNETH MAGIDSON
UNITED STATES ATTORNEY

By:


Jim McAlister
Assistant United States Attorney